



PROPOSED RULE MAKING

CR-102 (June 2004)

(Implements RCW 34.05.320)

Do **NOT** use for expedited rule making

Agency: Department of Labor and Industries

- ☒ **Preproposal Statement of Inquiry** was filed as WSR 06-01-068 ; or
☐ **Expedited Rule Making--Proposed notice** was filed as WSR _____; or
☐ **Proposal is exempt under RCW 34.05.310(4).**

- ☒ **Original Notice**
☐ **Supplemental Notice to WSR** _____
☐ **Continuance of WSR** _____

Title of rule and other identifying information: WAC 296-20-03002 Treatment not authorized, "artificial discs"

Hearing location(s):

Date: April 7, 2006 Time: 1:30 pm
 Department of Labor and Industries
 Room S 117
 7273 Linderson Way, SW
 Tumwater, WA 98501

Submit written comments to:

Name: Josh Morse
 Address: Office of the Medical Director
 PO Box 44321
 Olympia WA 98504-4321

e-mail mojo235@lni.wa.gov

fax (360)902-6315 by (date) April 14, 2006, 5pm

Assistance for persons with disabilities: Contact

Office of Information and Assistance by March 24, 2006

TTY (360) 902-5797 or (360) 902-4941

Date of intended adoption: May 22, 2006

(Note: This is **NOT** the **effective** date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules: This rulemaking is being proposed to put into rule an existing medical coverage decision to not cover lumbar artificial discs. The purpose is to supervise the care and treatment of injured workers and victims of crime. The anticipated effect would be safer and more efficacious treatment. The Charite III disc, the only artificial disc approved by the Food and Drug Administration (FDA), was approved for marketing in 2004. Since that time, more than 70 serious adverse events have been reported to the FDA from its use.

Reasons supporting proposal: Lumbar artificial disc replacement is intended to address pain due to degenerative disc disease. The department reviewed the best scientific evidence on artificial discs and made a noncoverage decision because there was not substantial scientific support and thus the device has not been proven to be safe and efficacious. Putting this noncoverage decision in rule will give the department more legal support when challenged and ensure the safety of workers.

Statutory authority for adoption: RCW 51.04.020,
 RCW 51.04.030

Statute being implemented: RCW 51.04.020, RCW 51.04.030

Is rule necessary because of a:

Federal Law? ☐ Yes ☒ No
 Federal Court Decision? ☐ Yes ☒ No
 State Court Decision? ☐ Yes ☒ No
 If yes, CITATION:

CODE REVISER USE ONLY

WSR# 06-06-067

DATE

February 28, 2006

NAME (type or print)

Gary K. Weeks

SIGNATURE

TITLE Director

(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

This proposed language focuses on the only artificial disc currently approved by the federal Food and Drug Administration (FDA), lumbar artificial discs.

Name of proponent: (person or organization) Department of Labor and Industries

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Jamie Lifka	7273 Linderson Way SW, Tumwater	(360) 902-4941
Implementation.... Gary Franklin, MD, MPH	Medical Director	(360) 902-5020
Enforcement..... Bob Malooly	Assistant Director for Insurance Services	(360) 902-4209

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

☐ Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone () _____
fax () _____
e-mail _____

☒ No. Explain why no statement was prepared.

This administrative rule codifies current department policy. The policy is to not cover a particular medical device. The rule relates only to internal governmental operations, and the rule is not subject to violation by a nongovernment party. Additionally, an SBEIS is unnecessary because the rule is a mere codification of existing policy and no small businesses would be impacted by the adoption of this rule. Currently, by policy, the department does not pay for this treatment, providers have already been informed through a provider bulletin of department policy that this treatment is not covered, and putting this policy into rule does not affect any provider's revenue vis a vis the department.

Is a cost-benefit analysis required under RCW 34.05.328?

☐ Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

phone () _____
fax () _____
e-mail _____

☒ No: Please explain This administrative rule codifies current department policy. The policy is to not cover a particular medical device. The rule relates only to internal governmental operations, and the rule is not subject to violation by a nongovernment party.

Additionally, a cost benefit analysis is unnecessary. Currently, by policy, the department does not pay for this treatment, providers have already been informed through a provider bulletin of department policy that this treatment is not covered, and putting this policy into rule does not affect any provider's revenue vis a vis the department.